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EXAMINER	
WOITACH, JOSEPH T	
ART UNIT	PAPER NUMBER
1632	

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36

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.	Applicant(s)
09/484,629	Robinson et al.
Examiner	**Art Unit**
Joseph Woitach	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 20, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *8-16, 28, and 30-35* is/are pending in the application.

4a) Of the above, claim(s) *35* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *8-16, 28, and 30-34* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on February 20, 2003, paper number 35, has been entered.

DETAILED ACTION

This application is an original application filed January 18, 2000, which claims benefit to foreign applications: PCT/GB99/02658, filed December 8, 1998; 9817566.4, filed August 12 1998; and 9910522.3, filed May 6, 1999, all filed in the United Kingdom.

As indicted in the request for continued examination applicants amendment filed November 22, 2002, paper number 32 has been entered. The specification has been amended. Claims 8-10, 16, 28 and 31-34 have been amended. Claim 35 has been added. Claims 8-16, 28 and 30-35 are pending.

Election/Restriction

Newly submitted claim 35 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: In response to the restriction

requirement Applicants have elected groups II, claims 8-16 and 28, drawn to a nucleic acid encoding a 5'OT-EST polypeptide, a vector containing said nucleic acid and a cell containing said vector (see paper number 11 and 15). As indicated in the first office action, it was indicated that because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)) (see paper number 22, page 2). Newly submitted claim 35 is directed to a method of using a 5'OT-EST for determining mutations, polymorphisms or other changes. In the instant case, the inventions are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used to generate a protein or generate a transgenic animal. Further, the method of detecting a mutation can be performed using other products other than labeled probes of 5'OT-EST, such as PCR primer sequence derived from 5'OT-EST or surrounding sequences, or through the use of unlabeled probes and detection alternative means.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 35 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 8-16, 28 and 30-34 are currently under examination.

Sequence compliance

The specification is objected because this application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), however, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below. Specifically, Figure 6 contains multiple sequences which are not identified in the figure of the short description of the figure (see page 6). Identifying the sequences with the appropriate SEQ ID NO in the figure or description of the figure would obviate the basis of the objection.

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Specification

The disclosure objected to because the specification contains references to a URL is withdrawn.

The objection under 35 U.S.C. 132 because the amendment filed February 20, 2002, paper number 26 introduced new matter into the specification is withdrawn.

In each case amendments to the specification has obviated the basis of the objection.

Information Disclosure Statement

As requested by Applicants, a copy of the signed IDS filed July 18, 2000, paper number 6, is provided.

The listing of references in the specification is not a proper information disclosure statement (see pages 55-66). 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. This is noted because upon review of the references listed in the specification some are not listed in the IDS, for example Altchul *et al.* (1994).

Claim Objections

Claim 32 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, claim 31 is drawn to a nucleic acid which modulates the obesity of an animal in which it is expressed which is narrower than claim 8 which

is drawn to a sequence which would provide any phenotype, in particular no affect on obesity. However, claim 32 simply recites that the obesity is modulated in a transgenic animal instead of any animal. Claims 31 and 32 encompass a particular polynucleotide, not the intended use of said nucleotide. Since claims 31 and 32 encompass a polynucleotide which provides the same phenotype, the polynucleotide encompassed by both claims are the same.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 28 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". In the instant case, a probe 'of 150 nucleotides or less' is considered new matter. Applicants have not specifically pointed to the portion of the specification for support of this amendment. Upon review of the

specification literal support for this amendment can not be found. Support for a probe which is preferably 5 to 150 nucleotides is found on page 15, second to last paragraph. However, this length is not specifically associated with probe to detect mutations or polymorphisms which predispose an individual to obesity rather it is only associated with sequences which are related to fragments which encode a polypeptide henceinbefore defined in the specification.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claim 28 is also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed,

involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

Claims 8-16, 28 and 30-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The final Written Description Examination guidelines that were published on January 5, 2001 (66 FR 1099; available at http://www.uspto.gov/web/menu/current.html#register).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d

at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998).

In the instant case, the specification fails to adequately describe a nucleic acid encoding a 5'OT-EST polypeptide which is 90% homologous to the polypeptide set forth in SEQ ID NO:2, 4-7, 16, or 17 and the polynucleotide set forth SEQ ID NO: 1, 3, or 31. The specification does not define any specific or critical features of a 5'OT-EST polypeptide sequence wherein the artisan would be able to distinguish whether a sequence would be considered a 5'OT-EST. Simply providing a percent homology to a particular SEQ ID NO fails to adequately describe any relevant identifying characteristics of a 5'OT-EST wherein the artisan sufficiently would recognize that the inventor had possession of the invention as broadly claimed. Further, the claims are broad encompassing specific sequences which are considered 'mutations, polymorphisms or other changes in 5'OT-EST which may predispose an individual to obesity' as

specifically claimed in claim 28 and implicitly in each of the claims encompassing the same structural limitations of 90% homology encompassed by all the claims. The specification is silent with respect to any mutation or polymorphism which is associated with obesity. The specification provides a transgenic rat, JP17, which demonstrates a disproportionate growth, however as indicate in the specification this growth pattern 'is well known in transgenic animals expressing hGH' which these transgenic animals express (page 50, Example 4, end of first paragraph). However, there is no clear link between this animal model and any affect of a 5'OT-EST and affects on obesity of the animal. Even more complicating, is the fact that it is not only the transgene itself, but rather the number of copies of the transgene which affect the growth. In particular, the specification teaches that two transgenic lines were made and characterized but unlike the JP17 line which contained 4 copies of the transgene, JP59 which contained only one copy of the transgene demonstrated no apparent phenotype (page 50, middle of first paragraph). It is noted that adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). In the instant case, the specification is silent with respect to any critical characteristic of a sequence which would be considered a 5'OT-EST. Further, beyond the specific SEQ ID NOs defined to be a 5'OT-EST

sequence, the specification is silent with respect to what would be considered a mutation or a polymorphism of these specific sequences. Finally, the specification fails to provide a clear nexus between the SEQ ID NOs and there consequence on any assayable phenotype of a cell or transgenic animal wherein the artisan could even test any variation of the SEQ ID NO.

Applicants attention is drawn to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein it was stated:

In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

In the instant case, the specification fails to provide any specific or identifying feature of a 5'OT-EST beyond the specific sequences set forth as SEQ ID NOs. Accordingly, naming a type of

material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Reciting only the structural limitation of 90% homology fails to provide an adequate description or critical defining features wherein the artisan could distinguish any particular sequence as a 5'OT-EST.

Applicants summarize the basis of the rejection and note the amendments to the claims, in particular the recitation that sequences are 90% identical as determined by BLAST analysis using default values (pages 7-8). Applicants argue that one of skill in the art could readily determine if the sequences were encompassed by the claims because a homology analysis could be done. Further, Applicants argue that recitation of mutant or that the sequences encompass mutants is irrelevant and 'what matters is that the given nucleic acid encodes a polypeptide that has the structure defined by the claim' (page 8, middle paragraph). Further, it is argued that there is a structure function relationship in that expression of 5'OT-EST results in the modulation of obesity (pages 8-9). See Applicants' amendment, pages 7-9. Applicants' arguments have been fully considered but not found persuasive.

Examiner would agree, as indicated in Applicants arguments, the percent homology does provide for a structural limitation of the polynucleotide (see page 8, first full paragraph), however as discussed above in detail the structural limitation fails to describe any functional or critical

feature of a 5'OT-EST. Possession may be shown by clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Since the specification is silent with respect to any relevant identifying characteristic of a 5'OT-EST (neither for the polynucleotide nor the polypeptide sequences) the specification fails to provide any nexus between structure and function of a 5'OT-EST which the artisan could use to determine if a sequence with any given structural limitation would be considered a 5' OT-EST. Applicants arguments indicate that there is a structure function relationship between the 5'OT-EST sequence causing a modulation in weight, however the evidence of record suggests otherwise. Given the data comparing J17 and J45 transgenic lines, at most one could conclude that expression levels, not any variation of the sequence itself (of the 5'OT-EST) may affect weight gain. However, as indicated in the specification the weight gain seen in the transgenic rat is more consistent with the expression of hGH which is also present on the construct used and which has been previously described in the prior art. Applicants arguments are not persuasive because the specification fails to provide any identifying characteristics of the 5'OT-EST sequence, and thus fails to provide an adequate description demonstrating that Applicants were in possession of the invention as broadly claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-16, 28 and 31-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 9, 10, 16 and 28 are vague and indefinite in the recitation of 'at least 90% homologous... as determined by BLAST analysis using default parameters'. The specification makes reference to where BLAST programs can be found at the NCBI website but does not specifically define what particular BLAST program to use or specifically define what is considered to be default parameters within any of these programs. In this case, determining the metes and bounds of the claims depends on the program and the parameters. The specification teaches one can obtain different homology results based on the program and parameters chosen (see for example page 14; third full paragraph). The claims encompass the use of parameters which are not specifically defined and subject to change, therefore the metes and bounds of the claim are not substantively nor clearly defined. Further, multiple BLAST programs have been designed and exist (see for example NCBI website and reference to said site, page 12), and are subject to modification outside the context of the present specification. Finally, the default

parameters are not defined as those provided at any specific location, thus depending on the artisan who sets these parameters within their own analysis, again the default parameters one chooses to use could vary among specific users. Without specific guidance in the specification providing clear guidance to the specific nature of the program used and what is considered a default value within this program, the results of a homology search are subject to change as a program is updated or altered. Recitation of '90%' or any percentage does not adequately define the metes and bounds of the claim because the parameters of particular program can be adjusted wherein insertions and deletions can be made, or % homology is calculated by local similarities, where each change confers a potentially different search result. Given that multiple parameters can be altered, each giving rise to a different search and search result, the metes and bounds of the claim is not defined and indefinite. Dependent claims 11-16, 31 and 32 are included in the basis of the rejection because they encompass this embodiment and fail to further clarify the specific parameters or specific sequences encompassed by the claims from which they depend. It is noted that claims 33 and 34 recite specific SEQ IE NOs, however these do not encompass 90% of the entire sequence of SEQ ID NO: 1 and 3.

Applicants note the amendments to the claims and argue that given a specific algorithm and parameters, the skilled artisan would be able to determine the metes and bounds of the claim.

See Applicants amendment, page 10. Applicants' arguments have been fully considered, but not found persuasive. The amendments to the claims are noted, however as discussed above the present specification is silent with respect to any specificity about the algorithm or specific parameters of any BLAST program. Given that these are not specifically defined in the present specification and subject to change among individual users, the metes and bounds of the claims are indefinite.

Claim 9 is confusing and unclear in the recitation of a 'nucleic acid of claim 8, having sequences selected from the group consisting of SEQ ID NOs: 1, 3, 5, 7, 16 or 17' and limitations of sequences which hybridize because SEQ ID NOs: 5, 7, 16 and 17 are polypeptide sequences, not nucleic acid sequences.

Claim 28 is confusing with respect to the embodiment of the claim as the nucleic acid is drawn to being capable of hybridizing to SEQ ID NO: 5 because SEQ ID NO: 5 is a polypeptide sequence not a nucleic acid sequence.

Claim 30 is unclear and confusing because SEQ ID NO: 16 does not set forth exons w, x, y or z and is only the polypeptide sequence Pro Leu Trp Ile. Further, the claim is confusing because homology searches of SEQ ID NO: 16 does not indicate that each of the recited exons even encodes SEQ ID NO: 16.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8-12, 15, 16 and 28 rejected under 35 U.S.C. 102(b) as being anticipated by GenBank sequence entries: AA955566, AA421393, AA505752, AA421310, AA2422211, AA245389, AA104183, AA850004, H31115, or H31114 is withdrawn.

Amendments to the claims to encompass homology over the full length of the sequences set forth in SEQ ID NOs: 2, 4 or 6 has differentiated the claimed invention from that disclosed in the cited Genbank sequence entries. The cited Genbank sequences represent EST sequences which share partial homology. With respect to claim 28, the claim has been amended to recite that the sequences is '150 nucleotides or less'. Each of the cited sequences are greater than 150 base pairs in length.

Conclusion

No claim is allowed. The claims are free of the art of record because the art fails to teach or make obvious the specific SEQ ID NOs or homologous sequences encompassed by the present claims, however they are subject to other rejections. The TO and AVP genomic sequences have been previously described, however these cloned sequences did not contain the 5' polynucleotide sequence which comprised the 5'OT EST gene described in the instant specification. Further, the prior art teaches that ESTs sharing partial homology to the 5'OT EST sequences were known, however the art failed to teach the full length sequences as presently disclosed, and failed to appreciate the presence of the 5'OT EST gene 13 kb upstream of the TO gene, or provide motivation to link this gene or gene product described only by the partial EST sequences with the TO gene. The OT sequences described are demonstrated to be in physical linkage to Ptpra, AVp and Oxt and provide physical markers of these genes on chromosome 2 (specification-page 9).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

Joe Woitach

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